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EXAMINER
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ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,973	TRAN ET AL.	
	Examiner	Art Unit	
	ANNETTE F. DIXON	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amendment 12/2/10 and inteview 12/7/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35,37-44,55-57 and 59-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-35,37-44,55-57 and 59-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Four filed on 6/10/10 and one filed on 12/2/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on October 5, 2010, the interview conducted on November 30, 2010, and the new claim amendments submitted on December 2, 2010. Examiner acknowledges claims 28-35, 37-44, 55-57, and 59-65 are pending in this application, with claims 28, 43, and 57 having been currently amended, claims 60-65 having been newly added, and claim 1-27, 36, 45-54, and 58 having been cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 57 and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 57 now recites "the lumen extends through the proximal portion and the distal portion...where the lumen extends through the proximal portion in which a diameter of the lumen is reduced from a first diameter to a second diameter". This recitation is unclear because Examiner is unsure if the first diameter is located at the proximal or the distal end. From a review of Applicant's invention as described in Figure 4, it appears the second smaller diameter is characteristic of the distal portion and a portion of the proximal portion; while, the larger diameter is characteristic of the proximal portion of the catheter only. Dependent claims 60-62 incorporate the indefinite

subject matter from which they depend. For clarity Examiner requests Applicant explicitly recite the relationship of the diameters with respect to the distal and proximal portions of the catheter. Appropriate clarification is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 28-35, 37-44, 56 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198).

As to Claim 28, Saadat disclose a system for delivering a contraceptive device (50) within a fallopian tube (Figure 2), the system comprising: a catheter (100) comprising a lumen (110), a distal portion (101) and a proximal portion (107), a contraceptive device (50) releasably disposed at least partially within the lumen (110) of the catheter (100) near the distal portion (101); and a deployment member (120) in detachable engagement with the contraception device (50) for deploying the contraceptive device (50) from the catheter (100) (Figure 11, Figure 13, and Column 10, Lines 30-31). Yet, Saadat does not teach the particulars of the catheter having a coil disposed along the catheter body and extending along the distal and proximal portions, nor the varying degrees of flexibility and a radiopaque marker located between the portions of the distal and the proximal end. Berhow teaches a medical catheter (10)

having a coil (16) which extends along the length of the catheter from the distal end (13) to the proximal end (12) where along the catheter (10) the flexibility of the changes for the purpose of having a reinforced catheter with resistance to kinking that may result in trauma to the patient (Figures 1-4A, Paragraphs 0061 and 0071). Further, Berhow teaches outer layer (17) of the lumen (15) constrains the coil (16) and is made of varying durometers (hardness) along its length representative of changes in flexibility. (Paragraphs 0062 and 0063). Regarding the radiopaque marker, Berhow teaches the use of two types of radiopaque markers, the first type being admixed into the sheath (via filler 19) and the second type a tracer ring ("not shown" Paragraph 0059) on the catheter (10) to permit visualization of the catheter within the patient. (Paragraphs 0058 and 0059). For purposes of rejection, as there is no dimensions imparted to the length or characteristics of the distal portion versus the proximal portion of the continuous catheter, both types of radiopaque markers are capable of enhancing common region between the distal and the proximal end. Further, it should be noted due to the continuous nature of the catheter, the placement of the tracer ring proximate to the distal tip of the sheath can constitute the claimed common region between the distal and the proximal end. Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter of Saadat to include a coil having varying degrees of flexibility along the length of the catheter and to include radiopaque markers on the catheter as taught by Berhow to provide a reinforced catheter having additional safety features to prevent patient trauma as a result of kinking.

As to Claims 29, 37, 38, and 56 Berhow teaches the medical catheter is most flexible (or least hard) at the distal end and increasingly becomes less flexible (or more hard) towards the proximal end (12). (Paragraph 0061).

As to Claim 30, Berhow teaches the catheter (10) is made from multiple layers in the distal portion (13) and having a coil (16) in one of the layers. (Figures 1-3 and Paragraphs 0038 and 0051).

As to Claims 31-35 and 39-42, Berhow teaches the multiple layers comprise: an inner layer (14, polytetrafluroethylene), a middle layer (16, stainless steel coil) and an outer layer (17, polyurethane). (Figures 1-3 and Paragraphs 0019, 0021, 0024, 0038, and 0051).

As to Claims 43, 44, and 63, Berhow teaches the use of a radiopaque marker (19) or tracer ring on the catheter (10) to permit visualization of the catheter within the patient. (Paragraphs 0058 and 0059). As addressed in the rejection of claim 28, the catheter is continuous and as there are no dimensions or structural characteristics to define the scope of the distal and proximal portions, the placement of the tracer ring proximate to the distal tip is in fact located in the claimed common region between the distal and the proximal end.

As to Claim 64, Berhow teaches an exemplary catheter having four inches of reinforcement wherein the reinforcement terminates proximal to the distal end of the catheter shaft. (Paragraphs 0051 and 0052). Further Berhow teaches the four inches can be broken into 1 inch zones defined by the type of reinforcement member. As addressed in the rejection of claim 28, the catheter is continuous and consequently the

distal and proximal ends have a common region there between, Berhow's first inch of reinforcement versus the remaining length of the catheter is in fact the claimed common region between the distal and the proximal end as there are no claim limitations limiting the reinforcement member to only the distal end or lumen dimensions of the catheter. Regarding the claimed range of about 1.2 cm to about 2.0 cm, please note 1 inch is 2.54 cm, which is about 2.0 cm.

As to Claim 65, please see the rejection of claim 64. Berhow teaches the catheter may be between 12 to 48 inches in length. Please note the claimed length range is between 40 cm and 60 cm, or 15.75 inches and 23.62 inches. Consequently Berhow teaches a catheter that meets the recited length ranges.

6. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198), as applied to claim 28, and further in view of Shepherd (3,566,874).

As to Claim 55, the modified Saadat teaches a reinforced medical catheter for delivering a contraceptive device, yet does not expressly disclose the use of a hydrophilic coating over the distal portion of the catheter. Shepherd teaches the use a hydrophilic coating over the distal end of the catheter for the purpose of reducing the irritation and infection associated with the normal use of catheters. (Abstract). Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter of the modified Saadat to include a hydrophilic coating over the catheter as taught by Shepherd for the purpose of preventing infection.

7. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198), as applied to claim 28, and further in view of Peters (5,441,485).

As to Claim 59, the modified Saadat teaches a reinforced medical catheter for delivering a contraceptive device having flexibility as a result of differing durometers (hardness) along the length of the catheter. Yet, the modified Saadat does not expressly disclose the varying of the thickness of the catheter along its length for imparting flexibility. Peters teaches the manner of imparting flexibility to a catheter can be achieved by multitude of alternative manufacturing processes including but not limited to: varying the thickness, molding sections out of different materials each having different durometers, or a combination thereof. (Column 3, Line 28 thru Column 4, Line 1). Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter manufacturing method for imparting flexibility of the modified Saadat, to include the alternative catheter manufacturing method of varying the thickness of the catheter, as taught by Peters as an alternative method by which the catheter can have varying degrees of flexibility along its length.

8. Claims 57 and 60-62, as best understood by the Examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198), as applied to claim 28, and further in view of Wijay et al. (4,921,483).

As to Claim 57, the modified Saddat, specifically Berhow teaches a lumen (15) that extends throughout the catheter (10). (Paragraph 0038). Yet does not expressly disclose the lumen to have a first and second diameter at the distal and proximal portions of the catheter, wherein the first diameter is larger than the second diameter. Wijay teaches a catheter (c) having a lumen (12) with a tapered region (20) wherein the proximal portion of the catheter has a first diameter (16) that is larger than the second diameter (22) at the distal portion for the purpose of providing a low profile and minimally invasive ("avoid impeding blood flow") catheter for being used during medical procedures. (Column 5, Line 66 thru Column 6, Line 13). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lumen of the modified Saddat to include a tapered region as taught by Wijay to provide a low profile and minimally invasive catheter capable of being used in medical procedures.

As to Claim 60, the modified Saddat, specifically Berhow teaches a coil (one of 16, 34, and 46a) encircling the distal most segment of a catheter (one of 13, 36, and 40A) as seen in Figures 1, 4a and 5 resepctively.

As to Claims 61 and 62, the modified Saddat, specifically Berhow teaches the multiple layers comprise: an inner layer (14, polytetrafluroethylene), a middle layer (16, stainless steel coil) and an outer layer (17, polyurethane). (Figures 1-3 and Paragraphs 0019, 0021, 0024, 0038, and 0051).

Response to Arguments

9. Applicant's arguments with respect to claims, filed December 2, 2010, have been considered but are moot in view of the new ground(s) of rejection.

Regarding the combination of the Saadat in view of Berhow, Applicant asserts the newly recited imitations of "wherein the proximal portion joins the distal portion, and the proximal portion further comprises a visualization marker where the proximal portion joins the distal portion to enhance visualization of a proximal-most end of the distal portion" are not disclosed. However, Berhow teaches the use of two types of radiopaque markers, the first type being admixed into the sheath (via filler 19) and the second type a tracer ring (“not shown” Paragraph 0059) on the catheter (10) to permit visualization of the catheter within the patient. (Paragraphs 0058 and 0059). For purposes of rejection, as there is no dimensions imparted to the length or characteristics of the distal portion versus the proximal portion of the continuous catheter, both types of radiopaque markers are capable of enhancing common region between the distal and the proximal ends. Further, it should be noted due to the continuous nature of the catheter, the placement of the tracer ring “proximate to the distal tip of the sheath” can constitute the claimed common region between the distal and the proximal end. In light of the aforementioned reasoning, the rejection of the claims has been maintained despite the newly recited claim limitations.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNETTE F. DIXON whose telephone number is (571)272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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